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KUNZ, G

ELAINE P. BRENNER
CORPORATE PATENT COUNSEL
ENZO BIOCHEM, INC.
345 HUDSON STREET
NEW YORK, NY 10014

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DAT 10 1991

04/01/91

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire _____ month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-50 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☒ Claims 1-50 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 5 I. Claims 1 - 20 and 42 - 50, drawn to nuclease resistant oligonucleotides, classified in Class 536, subclass 27.
- 10 II. Claims 21 - 39, drawn to a method of inhibiting the function of an RNA, classified in Class 435, subclass 6.
- 15 III. Claim 40, drawn to a method of identifying a specific compound having nuclease resistance and the ability to form an RNase H substrate when in complex with an RNA.

The inventions are distinct, each from the other because of the following reasons:

20 Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used

25 in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as an affinity ligand in affinity chromatography.

30 Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

35 that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product as claimed can be made by screening modified nucleotides in vitro to select for those than inhibit the production of a specific RNA.

40 Inventions II and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined

45 along with the elected invention (M.P.E.P. § 806.05(i)).

50 Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Elaine Brenner on January 17, 1991, a provisional election was made with traverse to prosecute the invention of Group I, claims 1 - 20 and 42 - 50. Affirmation of this election must be made by applicant in responding to this Office action. Claims 21 - 41 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Claims 1 - 20 and 42 - 50 are generic to a plurality of disclosed patentably distinct species comprising modified oligonucleotides resistant to endo- and exonucleases. The applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

By election of species, the Examiner means an ultimate species from which a reasonable genus will be carved.

This ultimate oligonucleotide as defined by claim 1 would be one in which N, M, B, and x are given specific definitions. In other words, N is to be selected as either a phosphodiester bond or a specific modified phosphate bond such as 3'-methylphosphonate. M should be defined as a specific modified base or specific unmodified base, such as adenine, etc. B should be defined as a specific compound, whether a specific

protein or specific intercalating group, etc. X should be defined as a specific integer.

As part of election of species requirement, the applicant is requested to submit a claim directed to this ultimate
5 species alone.

As part of the applicant's duty to disclose under 37 CFR 1.56, the applicant is requested to submit copies of the ten most relevant references listed in the specifications.

Any inquiry concerning this communication or earlier
10 communications from the examiner should be directed to Examiner Kunz whose telephone number is (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Gary L. Kunz:glk
March 27, 1991

Johnnie R. Brown
JOHNNIE R. BROWN
SUPERVISORY PATENT EXAMINER
ART UNIT 183